REMARKS

Claims 2-4 are pending. In the Office Action mailed July 7, 2008, claim 2 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of USSN 11/656,226 and claims 7-9 of USSN 11/656,217. Claims 2-4 are rejected under 35 U.S.C. § 112, second paragraph, in that the term "subject in need thereof" is vague and indefinite. Claims 2-4 are rejected under 35 U.S.C. § 112, first paragraph in that the specification does not provide enablement for claims to all pharmaceutical substances. Claims 2-4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brewitt, US 5,629,286.

By this Amendment, Applicant amended claim 2 and added new claims 5-19. Support for new claims 5-19 may be found in the specification as filed (see below). No new matter has been added. Applicant would like to bring to the Examiner's attention co-pending unpublished application USSN 09/117,838, assigned to the same entity and having the same inventive entity which is directed to a method of making a bipathic medication comprising the steps of admixing an active medical substance and a homeopathic dilution of said active medical substance. By this disclosure, Applicant does not waive the right to keep the unpublished co-pending '838 application unavailable to the public. Applicant respectfully requests reconsideration and allowance of the pending claims in view of the amendments and remarks set forth below.

REJECTIONS UNDER 35 USC § 103(a)

Claims 2-4 are rejected under 35 USC § 103(a) as being unpatentable over Brewitt. The Examiner states that Brewitt teaches homeopathic activation of various growth factors through homeopathic dilutions and co-administration of mixtures of homeopathic dilutions of growth factors. From that, the Examiner concludes that

> "it would have been prima facie obvious to one of the ordinary skill in the art to optimize the efficacy of the composition by combining the active pharmaceutical substance with the homeopathically activated form of the same substances as claimed in the instant claims."

Applicant disagrees.

To establish a *prima facie* case of obviousness, three basic criteria must be met. See MPEP 2143.02; *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). First, there must be some teaching, suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine teachings of the prior art to achieve the claimed invention. Second, there must be a reasonable expectation of success. Finally, while the prior art reference (or references when combined) need not explicitly teach or suggest all the claim limitations, the Examiner must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. Thus, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Unless all of the three criteria are met, a conclusion of obviousness cannot be reached. MPEP §2141.02.

The teaching, suggestion or motivation test has been modified by *KSR Int'l v. Teleflex, Inc.* 127 S. Ct. 1727, 1741 (2007). To support obviousness, *KSR* still requires a showing that "there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l v. Teleflex, Inc*. 127 S. Ct. 1727, 1741 (2007).

The claims, as amended, are directed to methods of enhancing activity of specific active pharmaceutical substances, by treating the substance with a homeopathically activated form of the same substance. Applicant has discovered that when a therapeutic dose is combined with a homeopathic dose, the combination results in a potentiation of the pharmacological activity of the compound and/or reduction in the undesired side effects. (See specification page 2, last paragraph and page 3, last paragraph). Brewitt is directed to a composition that includes, *inter alia*, a mixture homeopathic dilutions of growth factors.

Applicant asserts that Brewitt does not teach, suggest or provide any reason to modify a therapeutic dose of a pharmaceutical substance in the manner of the claimed invention. Nor does it suggest or provide a reason to modify a homeopathic dilution. A person skilled in the art of homeopathic medicine would simply not look to use allopathic

technology in combination with a homeopathic dilution. Nor a person skilled in pharmacology would look to use homeopathic medicine in combination with pharmacology. As set forth above, KSR continues to require that the prior art provide a reason for the modification in the direction of the invention. Applicant respectfully directs the Examiner's attention to *Epstein Declaration* (submitted herewith). Epstein Declaration is unrebutted evidence that the art at the time of the filing of the present application simply did not provide one skilled in the art with the reason to modify the teachings of Brewitt in the direction of the claimed invention as a whole. The prior art could not have provided the requisite reason because the very reason for the modification is the essence of the present discovery. Thus, one skilled in the art would not have any reason, in view of Brewitt, to modify a therapeutic dose of a pharmaceutical substance in the direction of the claimed combination, leave alone to modify a homeopathic dilution of Brewitt to include a therapeutic dose.

In fact, Brewitt teaches away from using the pharmaceutical substance itself. Brewitt points out the differences between allopathic medicine and homeopathic medicine and states that use of "pharmacological doses of growth factors often have harsh side effects" (col. 3, lines 48-49) and that there are various "problems associated with the use of allopathic pharmaceuticals" for example, virus mutation (col. 4, lines 46-63).

The Examiner similarly did not set forth art that provides the requisite "reasonable expectation of success." The Office Action states as follows:

> The prior art discloses the same basic methodology, combining the same pharmaceutical substance in different states of activation to increase the activity of the pharmaceutical substance and administering to a subject. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success to optimize the efficacy of the composition by combining the active pharmaceutical substance with the homeopathically activated form of the same substances as claimed in the instant claims.

Applicant disagrees.

The art at the time the present application was filed did not provide one skilled in the art with any expectation of obtaining the results provided in the present application;

namely, that the homeopathically activated form will modify the properties of the therapeutic dose. Nor does the art provide an expectation of any other beneficial result from the use of the claimed combination. The specification shows that administration of the combination of the present invention is more potent than pharmaceutical substance alone or homeopathically activated dilutions of the active pharmaceutical substance alone, (see tables at pages 2, 3 and 5-7 of the specification), establishing that the treatment with homeopathic dilution significantly modifies the properties of a therapeutic dose of the substance. Applicant again respectfully directs the Examiner's attention to *Epstein Declaration* (submitted herewith), which is unrebutted evidence that the art, at the time of the filing of the present application, simply does not provide one skilled in the art of homeopathic medicine with any reason or expectation that using a therapeutic dose (allopathic medicine) in combination with homeopathic dilution would provide the results obtained in the present invention.

Nor does the Examiner set forth prior art that teaches or suggest all limitations of the amended claims. For example, independent claim 2, as amended, recites:

> A method of enhancing the activity of an active pharmaceutical substance, wherein said active pharmaceutical substance is phenazepam, said method comprising combining a therapeutic dose of said active pharmaceutical substance with a homeopathically activated form of said active pharmaceutical substance.

Independent claim 5 recites a method of enhancing the activity of diazepam. Independent claim 8 recites a method of enhancing the activity of hydrocortisone. Independent claim 11 recites a method of enhancing the activity of cyclophosphamide. Independent claim 14 recites a method of enhancing the activity of ethanol. Independent claim 17 recites a method of enhancing the activity morphine.

Brewitt does not provide any information with respect to phenazepam, diazepam, hydrocortisone, cyclophosphamide, ethanol or morphine. Thus all of the claims limitations of claims 2-19 are not found in the cited art.

In conclusion, the Examiner has failed to meet the criteria required to support a *prima facie* case of unpatentability. Applicant respectfully asserts that claims 2-4 and newly added claims 5-19 are not obvious over the cited reference and withdrawal of the rejection is respectfully requested.

REJECTIONS UNDER 35 USC § 112

The Examiner has rejected claim 2 as unpatentable under 35 USC § 112, second paragraph, in that the claim recites the term "subject in need thereof," which the examiner considers vague and indefinite because it is not clear who the subject would be and the condition of the subject. Amended claim 2 and the newly added independent claims 5, 8, 11, 14 and 17 clearly describe the subject as a subject suffering from a condition or disorder treatable by the claimed active pharmaceutical substance. Therefore, the rejection has been obviated.

The Examiner rejected claims 2-4 under 35 U.S.C. § 112, first paragraph, as too broad and not supported by the specification. The Examiner acknowledges that the specification is enabling for the method of enhancing activity of certain pharmaceutical substances such as phenazepam. However, the Examiner states that the specification does not provide enablement for all pharmaceutical substances. Without agreeing with the Examiner, claims 2-4 have been amended to recite a method of enhancing the activity of phenazepam. New claims 5-19 are directed to a method of enhancing the activity of other specific pharmaceutical substances. (see table below). Applicant respectfully asserts that the rejections had been obviated. Support for the new claims may be found in the specification, for example, as follows:

Claims	Pharmaceutical Substance	Page, Example(s)
2-4	phenazepam	Page 2, Example 1
5-7	diazepam	Page 3, Example 2
8-10	hydrocortisone	Page 5, Example 4
11-13	cyclophosphamide	Page 5, Example 5
14-16	Ethanol	Page 6, Example 6
17-19	morphine	Page 7, Example 7

OBVIOUSNESS-TYPE DOUBLE PATENTING

The Examiner provisionally rejected the claim 2 of the present application over co-pending and co-assigned applications on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of USSN 11/656,226 and claims 7-9 of USSN 11/656,217.

The Office Action states that

> "The instant claims recite a method of enhancing the activity of pharmaceutical substance for the administration to a subject comprising combining the substance with homeopathically activated substance. The above stated US Applications disclose a method of administration of activated forms antibodies to an antigen, wherein the activated form antibodies are produced by homeopathic technology and the activated forms antibodies (pharmaceutical agent) are administered together with this antigen and the antigen or hapten is a substance or a pharmaceutical agent." [emphasis added].

Applicants disagree.

The analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 USC 103(a) obviousness rejection. Thus, the factual inquiries set forth in *Graham v. John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966) that are applied for determining obviousness under 35 USC 103 are employed when making an obvious-type double patenting analysis. MPEP § 804.

Claim 2, as amended, is directed to methods of enhancing the activity of phenazepam, by combining a therapeutic dose of phenazepam with a homeopathically activated form of phenazepam.

Claims 1-3 of USSN 11/626,226 have been cancelled. The pending claims of USSN 11/626,226 are directed to a pharmaceutical agent comprising a homeopathically activated form of an antibody to a pharmaceutically active small molecule. Claim 7-8 of USSN 11/656,217 are directed to a method of treatment by administration of activated forms of ultra low doses of antibodies to an antigen, wherein said antigen is a pharmaceutical agent conjugated with high molecular compound (a hapten). Claim 9 of USSN 11/656,217 is directed to a method wherein the antibody and antigen are administered together. Thus, contrary to the Office Action, USSN 11/656,226 and USSN 11/656,217 do not disclose a method wherein the activated forms antibodies are pharmaceutical agents that are administered together with the antigen. Rather USSN 11/656,226 and USSN 11/656,217 disclose activated forms antibodies which are administered together with an antigen, the antigen being a pharmaceutical agent conjugated with high molecular compound (a hapten). Thus, it is the antigen which is a hapten not the antibody.

Applicant asserts that the requisite criteria, as set forth above on page 7, required for supporting obviousness have not been met. Neither USSN 11/656,226 nor USSN 11/656,217 teach, suggest or provide any reason to modify a therapeutic dose of phenazepam in the manner as claimed in claim 2. Nor does either USSN 11/656,226 or USSN 11/656,217 provide one of ordinary skill in the art with any expectation of obtaining the results provided in the present application. That is, that the homeopathically activated form of a pharmaceutical agent will modify the properties of a therapeutic dose of the same agent. Nor do either USSN 11/656,226 or USSN 11/656,217 teach or suggest all limitations of the amended claims. That is, neither application provides any information with respect enhancing the activity of phenazepam. Thus all of the claims limitations of claim 2 are not found in the above stated US Applications.

Thus, the Examiner has failed to meet the criteria required to support a case of

obviousness-type double patenting. Applicant respectfully asserts that claim 2 is not obvious over the pending claims of USSN 11/656,226 and claims 7-9 of USSN 11/656,217 and withdrawal of the rejection is respectfully requested.

The Applicant believes the rejections had been met and application is in condition for allowance. If the Examiner has any further concerns, the Examiner is respectfully requested to telephone the undersigned attorney. The fees for the Petition for Extension of Time and RCE are enclosed herewith. The Examiner is authorized to deduct additional fees believed due from our Deposit Account No. 50-4711.

Respectfully submitted,

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